

REMARKS

Applicants submit this response to an Office Action mailed by the USPTO on November 17, 2004 (the "Office Action"). Filed concurrently herewith is a Petition for Extension of Time to Reply by which applicants request a two (2) month extension of time for applicants to file a response to the Office Action. Thus, applicants' response is due no later than February 17, 2005,

Applicants resubmit this Amendment in response to the Office Action, in which the Examiner has noted that the listing of the claims previously submitted by applicants in their response mailed on August 10, 2004, did not include the text of all pending claims. Applicants hereby resubmit their previously filed amendment with a complete listing of all pending claims, including withdrawn claims.

In the Office Action, the Examiner has noted that claims 3-7 and 9-28 are withdrawn from further consideration. Although noted on the Office Action Summary, but not in the body of the Office Action, claims 30-33 are also withdrawn from the present application as being directed to a non-elect species. Also, applicants note that claim 8 recites a third stopper, which the Examiner has stated is directed to a non-elected species. The withdrawal of claims 8 and 30-33 are also reflected in the listing of the claims contained herein.

In the Office Action, the Examiner has rejected claims 1, 2 and 29 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,406,455 B1 to Willis et al. Applicants respectfully traverse that rejection. Willis et al. is directed to a needleless syringe in which two substances may be mixed prior to injection into the skin of a patient. The mixed substances are expelled from the syringe as a combined substance through an orifice 13 defined at an end of the

syringe. The device disclosed by Willis et al. is intended to “expel the drug through orifice 13 and into the skin.” See, e.g., column 7, lines 8-9. In addition, Willis et al. neither teaches nor suggests a spray device having spray nozzle for creating a spray suitable for inhalation by a patient, as now recited by applicants’ claims. Thus, applicants respectfully submit that Willis et al. fails to teach or suggest each element recited by the claims of the present application, as is required of a proper 35 U.S.C. §102 reference. Applicants further respectfully submit that the Examiner’s rejection of claims 1, 2 and 29 as being anticipated by Willis et al. is no longer tenable and respectfully request withdrawal of that rejection.

In the Office Action, the Examiner also rejected claims 1, 2, 8 and 29 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,923,448 to Ennis, III, in view of Willis et al. Applicants respectfully traverse that rejection. Ennis, III teaches a syringe having a cup-shaped nozzle tip that turbulently passes the liquid from the syringe as an atomized spray. See, e.g., Abstract. Willis et al. discloses that the orifice 13 is “designed so as to optimize the pressure profile,” and “for minimizing or eliminating the possibility of protein shearing when using protein based drugs.” See, e.g., column 7, lines 12-14, and column 9, lines 25-28. Applicants first respectfully take the position that a person skilled in the art would not combine the references as suggested by the Examiner, as they are not directed to solving the same problem (i.e., Willis et al. is directed to needleless injection devices, while Ennis, III is directed to delivery devices that atomize the medicament as it is expelled from the device). In addition, applicants respectfully submit that the Examiner’s proposed combination of Willis et al. and Ennis, III would render the device disclosed by Willis et al. inoperable, due to the importance of

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the design of the orifice 13 of Willis et al.; atomization of the substance as it is expelled from the device disclosed by Willis et al. would render that device inoperable. Thus, applicants submit that a person skilled in the art would not be motivated to make the combination proposed by the Examiner.

The distinguishing remarks set forth above with regard to Willis et al. and Ennis, III are also applicable to new claims 34 and 35. Thus, for the reasons set forth above with regard to those references, applicants respectfully submit that claims 34 and 35 are patentable over the prior art of record.

Applicants submit that the Examiner's rejection of claims 1, 2 and 28 as being unpatentable over the combination of Ennis, III and Willis et al. is no longer tenable, and respectfully request withdrawal of that rejection.

In view of the foregoing remarks, applicants respectfully submit that this amendment is fully responsive to the Office Action, and that claims 1, 2, 28 and 34-35 are patentable over the prior art of record in the present application, and are thus in condition for allowance. Applicants thus respectfully request early and favorable reconsideration of the present application.

Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this amendment, including those fees required in connection with applicants' Petition for Extension of Time, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

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Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

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